

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

**REDACTED VERSION**

----- X  
FERA PHARMACEUTICALS, LLC,

Plaintiff,

- against -

AKORN, INC., SEAN BRYNJELSEN, and  
MICHAEL STEHN,

Defendants.

Case No. 12 Civ. 07694 (LLS)

----- X  
AKORN, INC.,

Counterclaim-Plaintiff,

- against -

FERA PHARMACEUTICALS, LLC, ALFERA  
PHARMACEUTICALS, LLC, FERANDA,  
LLC, BACI 007, LLC, FERA HOLDINGS,  
LLC, PERRIGO COMPANY OF TENNESSEE,  
and PERRIGO COMPANY PLC,

Counterclaim-Defendants.

----- X  
  
**MEMORANDUM OF LAW IN SUPPORT OF COUNTERCLAIM-DEFENDANTS  
FERA PHARMACEUTICALS, LLC'S, ALFERA PHARMACEUTICALS, LLC'S,  
FERANDA, LLC'S, BACI 007, LLC'S, AND FERA HOLDINGS, LLC'S  
MOTION TO DISMISS THE COUNTERCLAIMS OF AKORN, INC.**

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Counterclaim-Defendants Fera Pharmaceuticals, LLC, Alfera Pharmaceuticals, LLC, Feranda, LLC, Baci 007, LLC, and Fera Holdings, LLC (collectively, “Fera”), by and through their attorneys, Napoli Bern Ripka Shkolnik LLP, respectfully submit this memorandum of law in support of their motion for an order, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, dismissing with prejudice the Counterclaims of Akorn, Inc. (“Akorn”).

### **PRELIMINARY STATEMENT**

Akorn’s counterclaims are nothing more than a failed attempt to feign non-existent injuries and misdirect the focus of this lawsuit. The counterclaims are insufficient for a number of reasons, not the least of which is that the evidence in Akorn’s possession (including its own documents, Fera’s documents, and documents obtained from third-parties) incontrovertibly refutes both the material factual allegations Akorn has asserted and the erroneous conclusions it has drawn. As detailed herein, the totality of the facts demonstrates that Akorn contracted with Fera solely to steal non-public information belonging to Fera for Akorn’s illicit benefit, and that Akorn succeeded. Now, having succeeded but unable to realize its anticipated ill-gotten gains due to nothing more than its own poor planning, Akorn has alleged several counterclaims in which it pretends to be the victim in order to distract the Court from Akorn’s abhorrent conduct in deceiving Fera, [REDACTED], the FDA (by knowingly allowing it to approve Akorn’s ANDA on the basis of incorrect information), and U.S. Customs (by importing Bacitracin API for Akorn’s own use under Fera’s end user letter in violation of federal law).

Akorn has raised claims for violations of antitrust law and tortious interference with business relations that rest on the faulty premise Akorn has been kept out of the Bacitracin market in the United States. Not so. Akorn has alleged that it is unable to commercialize Bacitracin in the U.S. without Sterile API (defined below) and has further alleged that non-party

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██████████ is the only supplier of Sterile API and has refused to supply it to Akorn. But as discussed below, because Akorn does not actually require Sterile API from ██████████ in order to commercialize Bacitracin in the U.S., the absence of that supply cannot possibly support Akorn's counterclaims and does not state an antitrust injury.

Akorn's suggestion that it was unlawfully blocked as a competitor in the Bacitracin market is also undercut by the fact that Akorn *cannot* have been a "competitor." Akorn contractually agreed not to enter the U.S. Bacitracin market during the life of its contract with Fera as Fera's contract manufacturer. But, Akorn then broke that promise when it submitted a Bacitracin ANDA to the FDA that essentially copied Fera's ANDA while the contract with Fera was still in effect. As Fera's contract manufacturer, Akorn promised not to misuse Fera's information and specifically promised *not* to compete with Fera for Bacitracin.

Akorn's strategy of distraction and inventive story-telling has failed to nudge its antitrust and tortious interference claims into the realm of plausibility. Certain facts Akorn has alleged in support of its counterclaims are not facts at all, either because the documentary evidence conclusively refutes them or because they are empty conclusions. Because the counterclaims' remaining slivers of fact are insufficient to support each and every one of its counterclaims, Akorn's counterclaims should be dismissed with prejudice.

### **STATEMENT OF FACTS AND RELEVANT ALLEGATIONS**

From 2009 through mid-2013, Fera was the only company with an active FDA-approved Abbreviated New Drug Application ("ANDA") for the sale of Bacitracin Ophthalmic Ointment, USP, 500 units/g ("Bacitracin") in the U.S. Bacitracin market. (Counterclaims ¶¶ 1, 29.)<sup>1</sup> Fera was established in 2009 and acquired the Bacitracin ANDA from Fougere shortly thereafter. (*Id.*

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<sup>1</sup> References to "Counterclaims ¶ \_\_\_\_" are to the Counterclaims of Akorn, Inc. dated December 8, 2014.

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¶ 26.) In 2009, several other companies also owned FDA-approved Bacitracin ANDAs, but those companies allowed their ANDAs to lapse, and those ANDAs remain inactive. (*Id.* ¶ 29.)

Akorn manufactures ophthalmic ointments and has been in the generic ophthalmic market for more than half a century. (Counterclaims ¶ 22.) After Fera acquired the ANDAs of eight ophthalmic products from Fougere – including the ANDA for Bacitracin – Fera contracted with Akorn in July 2009 for Akorn to manufacture those eight products for Fera. Specifically, Fera and Akorn entered into a Commercial Manufacturing and Supply Agreement (the “CMS”). (*Id.* ¶ 27.) Prior to its contract-manufacturing relationship with Fera that began in July 2009, Akorn had never manufactured Bacitracin for itself or for anyone else.

While Akorn alleges that it “developed its own Bacitracin ten years before Fera purchased Fougere’s rights” (Counterclaims ¶ 33), this statement is both misleading and untrue. Akorn did not develop FDA-approvable Bacitracin ten years before its relationship with Fera. Instead, what Akorn developed was a non-FDA-approved product that contained the active pharmaceutical ingredient (“API”) for Bacitracin in some unknown and untested formulation. Akorn’s decade-old Bacitracin ANDA, which it alleges it finally submitted to the FDA in 2011, had not been confirmed one way or the other to be FDA-approvable Bacitracin proper in 2001. Until receiving FDA approval that its formulation meets the requirements of Bacitracin, Akorn cannot claim to have developed Bacitracin at any point in time. Akorn has no factual basis to claim that it developed Bacitracin ten years prior to its relationship with Fera.

Between 1995 and 2000, Akorn bought Bacitracin from Fougere that Fougere had manufactured and distributed to Akorn for it to sell through private labeling (meaning Akorn purchased the Bacitracin product manufactured by Fougere but with Akorn’s label). But, Fougere exited the Bacitracin market when it sold its Bacitracin ANDA to Fera in 2009. Despite

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Akorn's prior sales of Bacitracin under private labeling, Akorn never manufactured Bacitracin by itself prior to becoming Fera's contract manufacturer for Bacitracin and using the information that Fera provided to Akorn for it to manufacture Bacitracin for Fera.

██, was the only FDA-qualified supplier of the pre-sterilized form of the API found in Bacitracin ("Bacitracin API"). (Counterclaims ¶¶ 1, 43.) The Counterclaims lack clarity in describing Bacitracin API, which can be delivered to an end user either in pre-sterilized form ("Sterile API") or in non-pre-sterilized form that the end user can sterilize, have the API supplier sterilize, or utilize as-is ("Non-Sterile API"). As with Sterile API, ██████ also supplies Non-Sterile API.

Akorn alleges that a decade prior to its relationship with Fera, Akorn made two batches of ophthalmic ointment containing Sterile API, which ██████ supplied. (Counterclaims ¶ 22.) Akorn made one of these batches in 1999 and made the other batch in 2001. (*Id.*) Akorn then allegedly prepared an ANDA for Bacitracin in 2001 based upon its 1999 and 2001 exhibit batches of ophthalmic ointment containing Sterile API. (*Id.* ¶ 23.) Akorn maintains it chose not to submit its 2001 ANDA because the market price for Bacitracin was too low relative to the cost of its production. (*Id.*) However, Fera cured this problem by increasing the price of Bacitracin in late 2009 upon Fera's initial launch of Bacitracin in the U.S. market. (*Id.* ¶¶ 29, 71.) Shortly thereafter in 2010, Akorn decided to finalize its decade-old Bacitracin ANDA that it had prepared in 2001 (*id.* ¶ 30) so that Akorn could also participate in a now-lucrative market.

The CMS expressly prohibited Akorn from commercializing Bacitracin for anyone but Fera during its term. Nonetheless, Akorn wholly ignored its obligations, acquired Sterile API from ██████ on December 16, 2010, and used a portion of that Sterile API for Akorn's third

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exhibit batch (meant to supplement Akorn's 2001 ANDA). (Counterclaims ¶ 30.) Akorn's actions in this regard are in complete violation of the CMS.

Akorn did not tell [REDACTED] that it was finalizing the 2001 Bacitracin ANDA and did not tell [REDACTED] that Akorn intended to make its third exhibit batch of ophthalmic ointment using the Sterile API purchased on December 16, 2010. Nor does Akorn allege otherwise. Rather, Akorn claims that it was "completely forthright" in explaining to [REDACTED] it was buying some Sterile API for use in the Bacitracin that Akorn manufactured for Fera under the CMS, and some Sterile API to support an "Akorn core product launch." (Counterclaims ¶ 30.) In June 2011, without ever advising [REDACTED] that its "core product launch" was Bacitracin ophthalmic ointment, Akorn finalized and submitted the alleged 2001 ANDA to the FDA, in which Akorn included an outdated Letter of Authorization (LOA) from [REDACTED] that was dated November 2008 (*id.* ¶¶ 1, 31) without [REDACTED] knowledge. (*See* Brick Decl. Exh. 1 (emails between Akorn and [REDACTED])).<sup>2</sup>

In May 2012, Akorn improperly terminated the CMS with Fera. (Counterclaims ¶ 32.) By that time, of the eight products the CMS governed, Akorn had already refused to manufacture seven of those products for Fera – having claimed "capacity" restraints only a few months after executing the CMS with respect to these seven products. Akorn had effectively whittled down the CMS to its manufacture only of Bacitracin for Fera. When Akorn terminated the CMS, it claimed that Fera had not satisfied the minimum orders the CMS requires, notwithstanding that the contract minimums were based on Fera's requirements for all eight products, and Akorn refused to manufacture seven of those products. Fera commenced this action against Akorn in September 2012 based upon Akorn's misconduct as alleged in the Amended Complaint. (*Id.*) In addition to seeking money damages, Fera sought to permanently enjoin Akorn from

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<sup>2</sup> References to "Brick Decl." are to the April 21, 2015 Declaration of Brian H. Brick submitted by Fera in support of this motion.

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commercializing Bacitracin with the use of the information and techniques that Akorn learned from Fera when Akorn became Fera's contract manufacturer under the CMS.

**The Fera-Perrigo Asset Purchase Agreement**

In November 2012 – two months after commencing this action – Fera entered into discussions with Perrigo for a potential sale of Fera's eight ophthalmic ointment products (including Bacitracin). (Counterclaims ¶ 40.) After successful discussions, Fera and Perrigo entered into an Asset Purchase Agreement on June 14, 2013 (the "APA") by which Fera sold to Perrigo certain of its ophthalmic ANDAs including its Bacitracin ANDA. (*Id.* ¶¶ 3, 5, 41, 52.)

Akorn alleges it has lost millions of dollars in lost sales volume and profits because of the APA and specifically, because of a provision in the APA titled "[REDACTED]." (*Id.* ¶¶ 7, 54-55.) The [REDACTED] literally operates [REDACTED]

[REDACTED] under two relevant provisions in the APA. (Counterclaims Exh. I.) The [REDACTED] is a recognition of the risk to the value of the Bacitracin ANDA Fera was selling to Perrigo posed by Akorn's conduct and its possession of Fera's proprietary information for making Bacitracin.

Under the first provision of the [REDACTED]

[REDACTED]. (Counterclaims ¶ 54 and Exh. I § 2.8.) Importantly, although Fera sought (and continues to seek) this permanent injunction as a remedy for its claims alleged in the Amended Complaint, Fera commenced this action months prior to any discussions with Perrigo as a potential suitor

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(and almost a year prior to executing the APA). Thus, Fera has sought a permanent injunction against Akorn separate and apart from its later relationship with Perrigo. This particular provision of the [REDACTED]

[REDACTED].

Akorn's attempt to frame the APA's [REDACTED] provision as supporting its counterclaims is a logical fallacy. If Fera obtains the injunction it has sought (and continues to seek) through this lawsuit, then Fera is immediately entitled to [REDACTED].

But, [REDACTED]

[REDACTED], Fera will continue to seek an injunction in connection with its claims against Akorn in the Amended Complaint despite [REDACTED]

[REDACTED]. The APA does not [REDACTED]  
[REDACTED].

Under the second provision of the [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED].

(Counterclaims ¶ 55 and Exh. I § 2.8.) This second provision [REDACTED]

[REDACTED] in the APA between Fera and Perrigo that recognizes the substantial risk of Akorn's misappropriation or misuse of the information it received about Bacitracin from Fera. And, the plain language of the [REDACTED] does not concern [REDACTED]. This second provision cannot plausibly operate, or even conceivably be intended to operate, as an

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interference in any manner whatsoever with the U.S. Bacitracin market – which wholly subverts Akorn’s reliance on this provision to support its antitrust claims.

Akorn’s allegations (i) that it has lost millions of dollars in lost sales volume and profits because of the APA (Counterclaims ¶ 7), (ii) that the APA has and will continue to artificially reduce or eliminate competition in the U.S. Bacitracin market (*id.* ¶ 91), (iii) that the APA has and will continue to have the unreasonably anticompetitive effect of monopolizing the generic market for Bacitracin in the U.S. (*id.* ¶ 95), and (iv) that the APA is the reason that Akorn is unable to market and sell Bacitracin in the U.S. (*id.* ¶ 96) are all factually impossible. With no injury proximately caused by the APA, the APA cannot possibly support Akorn’s counterclaims.

### **The [REDACTED] Agreement**

Many months prior to its sale to Perrigo, Fera entered into negotiations with [REDACTED] through which [REDACTED] offered an exclusive supply of Sterile API to Fera for ophthalmic use in the United States but only on a requirements basis and only if [REDACTED] received a royalty on Fera’s U.S. sales of Bacitracin. (Counterclaims ¶ 44, *et seq.* and Exh. H.) Fera agreed to these conditions (among others), which were memorialized in the [REDACTED] Agreement, executed by and between [REDACTED] and Fera on June 14, 2013. (*Id.* ¶ 48.) The [REDACTED] Agreement is one of the contracts that Perrigo assumed in the APA. (*Id.* ¶¶ 5, 52.)

Akorn does not describe some of the important limitations contained in the [REDACTED] Agreement, including that it does not impact the sale of Sterile API for use in non-ophthalmic ointment products and does not impact the sale of Non-Sterile API for use in the manufacture of Bacitracin ophthalmic ointment. (Counterclaims Exh. H § 2(a).) And, the exclusive supply arrangement for Sterile API could be terminated if [REDACTED] sold the ownership rights of Sterile API to a third party. (*Id.* § 7(b)(iii).)

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In accordance with the [REDACTED] Agreement, [REDACTED] revoked any and all outstanding LOAs for Sterile API, notified the FDA of those revocations, and agreed not to issue any new LOAs for Sterile API. (Counterclaims ¶¶ 5, 49.) Akorn alleges that before Fera's sale to Perrigo, [REDACTED] had not indicated to Akorn that it intended to revoke the 2008 LOA and did not give Akorn a copy of its communication [with the FDA] revoking the 2008 LOA. (*Id.* ¶¶ 43, 66.) Akorn claims that because the [REDACTED] Agreement contained a confidentiality provision, Akorn was unaware that it would be unable to source Sterile API from [REDACTED] (*id.* ¶¶ 51, 66), and thus Akorn "waited for the FDA to approve its pending ANDA, believing that it would be able to enter the market in the first quarter of 2014." (*Id.* ¶ 66). This is simply not true and is wholly contradicted by communications between Akorn and [REDACTED].

In June 2013, six months prior to the FDA's December 2013 approval of Akorn's Bacitracin ANDA (Counterclaims ¶ 67), the following exchange occurred among [REDACTED] regulatory affairs director ([REDACTED]), [REDACTED] global technical support manager ([REDACTED]), and Akorn's corporate purchasing and procurement manager ([REDACTED]):

[REDACTED] wrote:

[REDACTED]

[REDACTED]

(*See* Brick Decl. Exh. 1 (emphasis added).)

[REDACTED] responded:

[REDACTED]

the 1990s, the number of people in the United States who are 65 years of age and older has increased by 50 percent, and the number of people 75 years of age and older has increased by 100 percent. The number of people 85 years of age and older has increased by 200 percent. The number of people 95 years of age and older has increased by 400 percent. The number of people 100 years of age and older has increased by 1,000 percent. The number of people 105 years of age and older has increased by 2,000 percent. The number of people 110 years of age and older has increased by 4,000 percent. The number of people 115 years of age and older has increased by 8,000 percent. The number of people 120 years of age and older has increased by 16,000 percent. The number of people 125 years of age and older has increased by 32,000 percent. The number of people 130 years of age and older has increased by 64,000 percent. The number of people 135 years of age and older has increased by 128,000 percent. The number of people 140 years of age and older has increased by 256,000 percent. The number of people 145 years of age and older has increased by 512,000 percent. The number of people 150 years of age and older has increased by 1,024,000 percent. The number of people 155 years of age and older has increased by 2,048,000 percent. The number of people 160 years of age and older has increased by 4,096,000 percent. The number of people 165 years of age and older has increased by 8,192,000 percent. The number of people 170 years of age and older has increased by 16,384,000 percent. The number of people 175 years of age and older has increased by 32,768,000 percent. The number of people 180 years of age and older has increased by 65,536,000 percent. The number of people 185 years of age and older has increased by 131,072,000 percent. The number of people 190 years of age and older has increased by 262,144,000 percent. The number of people 195 years of age and older has increased by 524,288,000 percent. The number of people 200 years of age and older has increased by 1,048,576,000 percent. The number of people 205 years of age and older has increased by 2,097,152,000 percent. The number of people 210 years of age and older has increased by 4,194,304,000 percent. The number of people 215 years of age and older has increased by 8,388,608,000 percent. The number of people 220 years of age and older has increased by 16,777,216,000 percent. The number of people 225 years of age and older has increased by 33,554,432,000 percent. The number of people 230 years of age and older has increased by 67,108,864,000 percent. The number of people 235 years of age and older has increased by 134,217,728,000 percent. The number of people 240 years of age and older has increased by 268,435,456,000 percent. The number of people 245 years of age and older has increased by 536,870,912,000 percent. The number of people 250 years of age and older has increased by 1,073,741,824,000 percent. The number of people 255 years of age and older has increased by 2,147,483,648,000 percent. The number of people 260 years of age and older has increased by 4,294,967,296,000 percent. The number of people 265 years of age and older has increased by 8,589,934,592,000 percent. The number of people 270 years of age and older has increased by 17,179,869,184,000 percent. The number of people 275 years of age and older has increased by 34,359,738,368,000 percent. The number of people 280 years of age and older has increased by 68,719,476,736,000 percent. The number of people 285 years of age and older has increased by 137,438,953,472,000 percent. The number of people 290 years of age and older has increased by 274,877,906,944,000 percent. The number of people 295 years of age and older has increased by 549,755,813,888,000 percent. The number of people 300 years of age and older has increased by 1,099,511,627,776,000 percent. The number of people 305 years of age and older has increased by 2,199,023,255,552,000 percent. The number of people 310 years of age and older has increased by 4,398,046,511,104,000 percent. The number of people 315 years of age and older has increased by 8,796,093,022,208,000 percent. The number of people 320 years of age and older has increased by 17,592,186,044,416,000 percent. The number of people 325 years of age and older has increased by 35,184,372,088,832,000 percent. The number of people 330 years of age and older has increased by 70,368,744,177,664,000 percent. The number of people 335 years of age and older has increased by 140,737,488,355,328,000 percent. The number of people 340 years of age and older has increased by 281,474,976,710,656,000 percent. The number of people 345 years of age and older has increased by 562,949,953,421,312,000 percent. The number of people 350 years of age and older has increased by 1,125,899,906,842,624,000 percent. The number of people 355 years of age and older has increased by 2,251,799,813,685,248,000 percent. The number of people 360 years of age and older has increased by 4,503,599,627,370,496,000 percent. The number of people 365 years of age and older has increased by 9,007,199,254,740,992,000 percent. The number of people 370 years of age and older has increased by 18,014,398,509,481,984,000 percent. The number of people 375 years of age and older has increased by 36,028,797,018,963,968,000 percent. The number of people 380 years of age and older has increased by 72,057,594,037,927,936,000 percent. The number of people 385 years of age and older has increased by 144,115,188,075,855,872,000 percent. The number of people 390 years of age and older has increased by 288,230,376,151,711,744,000 percent. The number of people 395 years of age and older has increased by 576,460,752,303,423,488,000 percent. The number of people 400 years of age and older has increased by 1,152,921,504,606,846,976,000 percent. The number of people 405 years of age and older has increased by 2,305,843,009,213,693,952,000 percent. The number of people 410 years of age and older has increased by 4,611,686,018,427,387,904,000 percent. The number of people 415 years of age and older has increased by 9,223,372,036,854,775,808,000 percent. The number of people 420 years of age and older has increased by 18,446,744,073,709,551,616,000 percent. The number of people 425 years of age and older has increased by 36,893,488,147,419,103,232,000 percent. The number of people 430 years of age and older has increased by 73,786,976,294,838,206,464,000 percent. The number of people 435 years of age and older has increased by 147,573,952,589,676,412,928,000 percent. The number of people 440 years of age and older has increased by 295,147,905,179,352,825,856,000 percent. The number of people 445 years of age and older has increased by 590,295,810,358,705,651,712,000 percent. The number of people 450 years of age and older has increased by 1,180,591,620,717,411,303,424,000 percent. The number of people 455 years of age and older has increased by 2,361,183,241,434,822,606,848,000 percent. The number of people 460 years of age and older has increased by 4,722,366,482,869,645,213,696,000 percent. The number of people 465 years of age and older has increased by 9,444,732,965,739,290,427,392,000 percent. The number of people 470 years of age and older has increased by 18,889,465,931,478,580,854,784,000 percent. The number of people 475 years of age and older has increased by 37,778,931,862,957,161,709,568,000 percent. The number of people 480 years of age and older has increased by 75,557,863,725,914,323,419,136,000 percent. The number of people 485 years of age and older has increased by 151,115,727,451,828,646,838,272,000 percent. The number of people 490 years of age and older has increased by 302,231,454,903,657,293,676,544,000 percent. The number of people 495 years of age and older has increased by 604,462,909,807,314,587,353,088,000 percent. The number of people 500 years of age and older has increased by 1,208,925,819,614,629,174,706,176,000 percent. The number of people 505 years of age and older has increased by 2,417,851,639,229,258,349,412,352,000 percent. The number of people 510 years of age and older has increased by 4,835,703,278,458,516,698,824,704,000 percent. The number of people 515 years of age and older has increased by 9,671,406,556,917,033,397,649,408,000 percent. The number of people 520 years of age and older has increased by 19,342,813,113,834,066,795,298,816,000 percent. The number of people 525 years of age and older has increased by 38,685,626,227,668,133,590,597,632,000 percent. The number of people 530 years of age and older has increased by 77,371,252,455,336,267,181,195,264,000 percent. The number of people 535 years of age and older has increased by 154,742,504,910,672,534,362,390,528,000 percent. The number of people 540 years of age and older has increased by 309,485,009,821,345,068,724,781,056,000 percent. The number of people 545 years of age and older has increased by 618,970,019,642,690,137,449,562,112,000 percent. The number of people 550 years of age and older has increased by 1,237,940,039,285,380,274,899,124,224,000 percent. The number of people 555 years of age and older has increased by 2,475,880,078,570,760,549,798,248,448,000 percent. The number of people 560 years of age and older has increased by 4,951,760,157,141,521,099,596,496,896,000 percent. The number of people 565 years of age and older has increased by 9,903,520,314,283,042,199,193,993,792,000 percent. The number of people 570 years of age and older has increased by 19,807,040,628,566,084,398,387,9

Despite claiming otherwise in the Counterclaims, Akorn knew – half a year prior to the FDA’s approval of its Bacitracin ANDA – that its ANDA contained material information that was false. Akorn intended for the FDA to rely on that false information, did not notify the FDA that that information was false, allowed the FDA to approve its ANDA based upon that material false information, and then feigned surprise when the FDA rescinded its approval of Akorn’s ANDA in February 2014 (Counterclaims ¶ 6), after “it was made aware” that [REDACTED] had revoked

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the 2008 LOA. (*Id.* ¶ 68.) And, Akorn was not the one to inform the FDA about the revocation of the 2008 LOA despite Akorn's express obligation to do so under federal law.<sup>3</sup>

Akorn also deceived U.S. Customs in importing Bacitracin API from [REDACTED] under an end user letter that only authorized the API for use in Fera's products. In order for Akorn to import Bacitracin API into the United States for its own use, it must do so under an end user letter that expressly states the API is for Akorn's own use. Instead, Akorn improperly imported Bacitracin API into the United States and used a portion for itself under Fera's end user letter.

Akorn, quite astutely, observes that the sole reason it is unable to market and sell Bacitracin in the U.S. is because it does not have an approved ANDA. (Counterclaims ¶ 69.) The reason Akorn does not have an approved ANDA has nothing to do with the [REDACTED] Agreement and is certainly not because Fera interfered with a Sterile API supply arrangement that Akorn clearly did not have – despite Akorn's conclusory allegations otherwise.

Akorn alleges that Fera engaged in misconduct and used heavy-handed tactics in order to obtain the [REDACTED] Contract. (Counterclaims ¶¶ 4, 45-46.) But this, as with Akorn's other erroneous conclusions, is implausible on its face. If anyone had leverage in negotiating the [REDACTED] Contract, it was [REDACTED]. If [REDACTED] is the only FDA-qualified supplier of Sterile API, and if Sterile API is a necessary ingredient in Bacitracin as Akorn alleges (*i.e.*, the FDA would be unwilling to approve the sterilization of Non-Sterile API) (Counterclaims ¶¶ 1, 47, 79), then [REDACTED] would have nothing to gain by agreeing to supply Sterile API only to Fera to the exclusion of potential others. That is because, assuming the truth of Akorn's allegations, Fera would have no choice but to order Sterile API from [REDACTED] if the FDA permitted only the use of Sterile API, meaning that [REDACTED] would have had the upper hand on the [REDACTED] Contract, not Fera.

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<sup>3</sup> 21 C.F.R. § 314.70(b)(1) required Akorn to report to the FDA any change to the drug substance in its pending Bacitracin ANDA and to submit a supplement detailing the changes for approval..

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Conversely, because the [REDACTED] Agreement concerns only Sterile API, if there is no regulatory bar for a manufacturer (*e.g.*, Akorn) to use Non-Sterile API and to sterilize it as a part of the manufacturing process, then Akorn's assertions that Fera's intent was solely to harm Akorn completely fail. In other words, either (i) pre-sterilized API is the only way to produce FDA-approved Bacitracin, which means Fera has no leverage vis-à-vis [REDACTED], (ii) or pre-sterilized API is not the only way to produce FDA-approved Bacitracin, which means that while Fera may have leverage over [REDACTED], Akorn has no market-entry-barrier and thus no injury.

Nowhere does Akorn allege that the FDA requires the use of Sterile API or that there is a regulatory bar to the use of Non-Sterile API in manufacturing Bacitracin. Thus, a manufacturer need not use pre-sterilized API because Non-Sterile API can be sterilized after it is purchased. Because the [REDACTED] Agreement does not impact Akorn's ability to purchase Non-Sterile API from [REDACTED], Akorn cannot plausibly allege that Fera kept Akorn from entering the Bacitracin market or that there are any barriers to Akorn's entry into the Bacitracin market.

Finally, Akorn alleges that Fera engaged in certain conduct in or around June 2013 "with the specific aim of disrupting Akorn's entry into" the U.S. market for Bacitracin. (Counterclaims ¶¶ 1, 45-51, 58-65.) But, this is factually impossible because prior to the June 20, 2013 communication between Fera and [REDACTED] referred to in the Counterclaims (*id.* ¶ 60), Fera did not know about Akorn's Bacitracin ANDA. Nor does Akorn allege any *facts* to show how Fera knew about Akorn's Bacitracin ANDA before June 20, 2013. Instead, Akorn intentionally kept its Bacitracin ANDA hidden from Fera to shield itself from contractual liability to Fera because Akorn was obligated not to manufacture Bacitracin for anyone except Fera – including for itself. The Counterclaims show that Fera had already entered into both the

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██████████ Agreement and the APA by the time it learned about Akorn's ANDA. As such, Akorn's allegation that Fera intended to disrupt approval of its Bacitracin ANDA is implausible.

While Fera may have had reasonable grounds based upon the circumstantial evidence (alleged in the Amended Complaint) to believe that Akorn had misappropriated trade secreted information (among other unlawful acts), Fera did not know for certain what Akorn would do with Fera's proprietary information. Among the possibilities were for Akorn to have illicitly sold Fera's trade secrets to a third party instead of Akorn using those trade secrets for its Bacitracin ANDA. Aside from the *ipse dixit* of specific mal-intent, tacked to Fera's otherwise lawful conduct, Akorn has failed to allege any facts that support even an inferential plausibility that Fera intended to disrupt Akorn's Bacitracin ANDA or that Fera harmed competition in the U.S. Bacitracin market.

### **ARGUMENT**

A motion to dismiss a counterclaim is evaluated under the same standard as a motion to dismiss a complaint. *Revonate Mfg., LLC v. Acer Am. Corp.*, No. 12 Civ. 6017, 2013 WL 342922, at \*2 (S.D.N.Y. Jan. 18, 2013) (citation omitted). Akorn's counterclaims cannot survive Fera's motion to dismiss under Rule 12(b)(6) because they do not "contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotes omitted). Akorn's conclusory assertions and formulaic recitations of the elements of a cause of action are insufficient. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). On a Rule 12(b)(6) motion, although the Court's review is typically "limited to the facts asserted within the four corners of the complaint, the documents attached to the complaint as exhibits, and any documents incorporated in the complaint by reference," *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 191 (2d Cir. 2007), the Court

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may also look to documents that Akorn has possession or knowledge of, or that Akorn relied upon in drafting the counterclaims. *See Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002).<sup>4</sup> Because Akorn “ha[s] not nudged [its] claims across the line from conceivable to plausible, [its] complaint must be dismissed.” *Twombly*, 550 U.S. at 570.

## I.

### **AKORN LACKS STANDING FOR COUNTS I AND II BECAUSE IT HAS FAILED TO ALLEGE AN “ANTITRUST INJURY”**

Counts I and II of the Counterclaims should be dismissed because Akorn has failed to meet a critical pre-requisite: alleging an “antitrust injury” – an injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants’ acts unlawful. *See Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977); *Balaklaw v. Lovell*, 14 F.3d 793, 797 (2d Cir. 1994). The antitrust injury requirement exists independently of the elements of an antitrust violation as a separate pleading requirement. *See In re Nine West Shoes Antitrust Litig.*, 80 F. Supp. 2d 181, 186 (S.D.N.Y. 2000) (noting standard separately imposed by Sections 4 and 16 of the Clayton Act, which confer antitrust standing on private plaintiffs).

To establish an antitrust injury, Akorn must show (1) an injury in fact, (2) that was caused by the violation, and (3) that it is the type of injury contemplated by the statute. *See Mathias v. Daily News, L.P.*, 152 F. Supp. 2d 465, 478 (S.D.N.Y. 2001) (“the harm must result from a competition-reducing aspect or effect of defendant’s behavior, and it must flow from conduct that the antitrust laws clearly condemn”) (citations omitted). Here, Akorn has not alleged – and cannot allege – facts showing that Fera’s conduct was causally connected to any injury to competition. The only purported injury to competition that Akorn asserts (as opposed

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<sup>4</sup> As relevant here, Fera refers the Court to Exhibit 1 to the Brick Declaration, an email exchange between Akorn and [REDACTED] that [REDACTED] produced to the parties in response to a subpoena *duces tecum*. Akorn certainly had knowledge of Exhibit 1 because it was a party to that email.

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to purported injury to Akorn) is that consumers have to pay artificially inflated prices for generic Bacitracin. (Counterclaims ¶¶ 7, 29, 71, 87.)

Akorn specifically alleges that Fera raised the price of Bacitracin in 2009 when it purchased the Bacitracin ANDA from Fougera. (*Id.* ¶¶ 29, 71.) But, throughout the Counterclaims, Akorn alleges a scheme between Fera and Perrigo that did not begin until late 2012 – several years *after* Fera raised the price of Bacitracin. (*Id.* ¶¶ 40, 90, 99.) Akorn does not allege a single fact showing any purportedly anti-competitive behavior before late 2012. Because the purported injury to competition in the form of increased prices happened several years before the purported anti-competitive conduct, that alleged injury cannot possibly have been caused by any conduct by Fera that violates antitrust laws. This lack of any causal connection is fatal to all of Akorn’s antitrust claims. *See World Wrestling Entertainment, Inc. v. Jakks Pacific, Inc.*, 425 F. Supp. 2d 484, 522-23 (S.D.N.Y. 2006); *Mathias*, 152 F. Supp. 2d at 477-80.

It is well-established that a primary goal of the antitrust laws is the protection of consumers. *See In re Nine West Shoes*, 80 F. Supp. 2d at 187; *Balaklaw*, 14 F.3d at 797 (antitrust laws are meant to protect competition and not competitors). Although an injury in fact may be that consumers have paid higher prices, those higher prices must be *a result of Fera’s anticompetitive conduct* to constitute “antitrust injury.” *See Associated Gen. Contractors of Calif., Inc. v. Calif. State Council of Carpenters*, 459 U.S. 519, 538 (1983); *In re Nine West Shoes*, 80 F. Supp. 2d at 187 (“consumers may suffer a particular kind of antitrust injury . . . when the price of those goods or services is artificially inflated *by reason of* the anticompetitive conduct complained of”) (emphasis added) (citation omitted). Although “the harm must result from a competition-reducing aspect or effect of defendant’s behavior, and it

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must flow from conduct that the antitrust laws clearly condemn,” *Mathias*, 152 F. Supp. 2d at 478 (citing *Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 344 (1990); *Brunswick Corp.*, 429 U.S. at 489), Akorn’s Counterclaims demonstrate this is not the case here.

Allegations of injury to competitors alone, no matter how numerous or conclusory, are insufficient to state antitrust injury. *See Mathias*, 152 F. Supp. 2d at 478-79 (citations omitted) (finding lack of antitrust injury because allegations of injury show only that carriers themselves were injured by alleged exclusionary conduct); *see also USAirways Group, Inc. v. British Airways PLC*, 989 F. Supp. 482, 488 (S.D.N.Y. 1997) (explaining USAir did not allege injury to competition in the U.S.-U.K. passenger air service market, separate from injury to itself – asserting only that plaintiffs’ actions foreclosed and excluded USAir from being an effective competitor in the U.S.-U.K. market – which is not the type of injury antitrust laws were intended to prevent). Akorn makes the same insufficient allegations in the Counterclaims that were faulty in *USAirways Group* because it alleges that Fera’s and Perrigo’s scheme had “the specific aim of disrupting *Akorn*’s imminent entry into [the Bacitracin] market.” (Counterclaims ¶ 1 (emphasis added).)

Akorn maintains that “[REDACTED]

[REDACTED]

[REDACTED] The injury caused by Fera’s and Perrigo’s actions include [Akorn’s] lost sales volume and lost profits.” (Counterclaims ¶ 85 (emphasis added).) The Counterclaims emphasize the purported harms *Akorn* has suffered from its alleged foreclosure from the Bacitracin market, but the only allegation Akorn offers with respect to any impact on competition is its conclusory assertion that consumers are being charged artificially inflated prices for generic Bacitracin – nothing else. (*Id.* ¶ 87.) According to Akorn,

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“U.S. consumers have been significantly harmed” and “the absence of competition has adversely affected consumers, who have been forced to pay artificially inflated prices for Bacitracin.” (*Id.* ¶ 7.) But Akorn pleads no *facts* showing Bacitracin’s prices are artificially inflated or explaining why they are artificially inflated – only Akorn’s conclusory assertions. Nor does Akorn allege any facts that plausibly show any such price increases were caused by Fera’s and Perrigo’s purported scheme to keep Akorn out of the Bacitracin market through the APA and the [REDACTED] Agreement. The harm to consumers that Akorn alleges *pre-dates* the purported anti-competitive conduct Akorn uses to support its claims. As a result, Akorn’s alleged antitrust injury is factually implausible, and Akorn lacks standing to allege antitrust claims.

## II.

### **AKORN HAS FAILED TO STATE A CLAIM AGAINST FERA UNDER SECTION 1 OF THE SHERMAN ANTITRUST ACT (15 U.S.C. § 1)**

Akorn has failed to allege a violation of Section 1 of the Sherman Act because Akorn cannot demonstrate: (i) a combination or some form of concerted action between at least two legally distinct economic entities that (ii) unreasonably restrains trade either *per se* or under the rule of reason. *See Virgin Atl. Airways Ltd. v. British Airways PLC*, 257 F.3d 256, 263 (2d Cir. 2001) (citation omitted). A claim of conspiracy in restraint of trade under the Sherman Act requires some form of joint action to exist to satisfy the “contracts, combinations, or conspiracy” requirement, and it is only after concerted action is found that the Court should address the second part of the analysis: whether the concerted activity is an unreasonable restraint of trade. *See Alabama Sportservice, Inc. v. Nat’l Horsemen’s Benev. & Protective Ass’n, Inc.*, 767 F. Supp. 1573, 1579 (M.D. Fla. 1991). Akorn’s claims should be analyzed under the rule of reason because none of Akorn’s allegations pleads a *per se* violation of Section 1 of the Sherman Act.

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Independent conduct falls outside the purview of Section 1. *See Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 761 (1984). Thus, to allege an antitrust conspiracy, “the antitrust plaintiff should present direct or circumstantial evidence that reasonably tends to prove that the [defendant] and others had a conscious commitment to a common scheme designed to achieve an unlawful objective.” *Id.* at 764 (citation omitted). Akorn’s factual allegations, stripped of their conclusory modifiers as detailed above in the Statement of Facts and Relevant Allegations, fail to show that Fera engaged in concerted activity or otherwise conspired to restrain trade.

Specifically, Akorn identifies only two agreements underlying its antitrust claims: the APA and the [REDACTED] Agreement. The APA is a purchase and sale agreement that effected a sale of the Bacitracin ANDA (among other products and assets) from Fera to Perrigo. Its terms do not implicate any restraints of trade as a matter of law. Although Akorn points to the [REDACTED] [REDACTED] as purported evidence of anti-competitive conduct, the express terms of the [REDACTED] [REDACTED] show it to be [REDACTED]

[REDACTED]. (Counterclaims Exh. I § 2.8.) The terms of the [REDACTED] do not require Fera to take *any* affirmative steps in order to obtain the holdback amount, and the mere passage of time without Akorn’s entry into the Bacitracin market entitles Fera to [REDACTED]. And, as for the provision for [REDACTED], Fera was already seeking such an injunction at the outset of this action, nine months before the APA was signed. The APA does not restrain trade in any manner, and its terms do not show any anti-competitive effect on the U.S. Bacitracin market.

The [REDACTED] Agreement likewise is subject to a rule of reason analysis as a vertical exclusive supply arrangement between Fera and [REDACTED]. *See, e.g., Leegin Creative Leather*

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*Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 882 (2007) (explaining vertical price restraints subject to rule of reason); *Pepsico, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 110 (2d Cir. 2002) (vertical exclusive dealing agreement presumptively lawful). “[I]t is settled law that the mere existence of an exclusive contract is not evidence of an antitrust conspiracy.” *Williamson v. Sacred Heart Hosp.*, No. 89 Civ. 30084, 1993 WL 543002, at \*45 (N.D. Fla. May 28, 1993) (rejecting conspiracy claim that was “essentially an attack on the economic validity of the exclusive contract”), *aff’d*, 41 F.3d 667 (11th Cir. 1994).

Under the rule of reason, Akorn has failed to satisfy its burden to demonstrate that Fera’s challenged behavior had an actual adverse effect on competition as a whole in the relevant market. *See Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., Inc.*, 996 F.2d 537, 543 (2d Cir. 1993). Aside from simply alleging that Fera and Perrigo agreed to conspire in restraint of trade, none of Akorn’s alleged facts, together or apart, raise a plausible inference of conspiracy. Instead, Akorn offers only conclusory allegations in support of its claims. Specifically, Akorn alleges the existence of the [REDACTED] Agreement as the factual “cornerstone” inferring conspiratorial conduct. (Counterclaims ¶ 90.) However, Akorn has failed to plead a single concerted action, jointly made by Fera and Perrigo that predates the existence of the [REDACTED] Agreement.

The only joint actions Akorn alleges with respect to Fera and Perrigo occurred after Fera and [REDACTED] executed the [REDACTED] Agreement and include that (i) on June 24, 2013 Fera and Perrigo wrote a letter to [REDACTED] [REDACTED] Agreement, which at that time, had been recently assumed by Perrigo pursuant to the APA (Counterclaims ¶¶ 6, 63), and (ii) that on July 10, 2013 Fera and Perrigo followed up on that prior correspondence with [REDACTED]. (*Id.* ¶ 64.) The fact that Fera was no longer a party to the [REDACTED]

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█████ Agreement but wrote to █████ together with Perrigo regarding █████ performance of its obligations under that contract, does not give rise to a conspiracy. *See U.S. v. Trenton Potteries Co.*, 273 U.S. 392, 402-03 (1926) (noting the agreement or conspiracy in restraint of trade is what constitutes the violation, whether followed by efforts to carry it into effect or not). There are no factual allegations in the Counterclaims that show joint action between Fera and Perrigo regarding the █████ Agreement prior to or in connection with its execution – only conclusory assertions. In addition, *Noerr-Pennington* protection encompasses concerted efforts incident to litigation, such as prelitigation “threat letters.” *See McGuire Oil Co. v. Mapco, Inc.*, 958 F.2d 1552, 1560 (11th Cir. 1992); *see also Viva Optique, Inc. v. Contour Optik, Inc.*, No. 03 Civ. 8948, 2007 WL 4302729, at \*2 (S.D.N.Y. Dec. 7, 2007) (under *Noerr-Pennington* doctrine, litigation as well as concerted efforts incident to litigation may not serve as basis for antitrust claim”). Thus, Akorn’s allegations that Fera or Perrigo threatened █████ with legal consequences if █████ did not adhere to the █████ Agreement are immaterial to Akorn’s legally insufficient antitrust claims.

The Counterclaims contain no facts showing that Fera and Perrigo engaged in concerted action that unreasonably restrained trade. The innocuous or immaterial facts Akorn has juxtaposed with a host of conclusory allegations do not nudge Akorn’s Section 1 claim across the line of plausibility. Akorn’s Section 1 claim should be dismissed.

### **III.**

#### **AKORN HAS FAILED TO STATE A CLAIM AGAINST FERA UNDER SECTION 2 OF THE SHERMAN ANTITRUST ACT (15 U.S.C. § 2)**

To establish a claim of monopolization in violation of Section 2 of the Sherman Act, a plaintiff must demonstrate: “(1) the possession of monopoly power in the relevant market, and (2) the willful acquisition or maintenance of that power as distinguished from growth or

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development as a consequence of a superior product, business acumen, or historic accident.” *Pepsico*, 315 F.3d at 105. “[T]he possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive conduct.” *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004). An attempted monopolization claim under Section 2 requires “(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power.” *Pepsico*, 315 F.3d at 105 (citation omitted). Similar to Section 1 claims, a conspiracy to monopolize requires the same threshold showing of the existence of an agreement and concerted action. But, an attempted monopolization claim requires a showing of specific intent to destroy competition or to build the monopoly. *See D’Last Corp. v. Ugent*, 863 F. Supp. 763, 769 (N.D. Ill. 1994), *aff’d*, 51 F.3d 275 (7th Cir. 1995).

There is no question that Fera acquired the only active FDA-approved Bacitracin ANDA upon purchasing it from Fougera in 2009, thereby inheriting a *de facto* monopoly. But, Akorn has failed to show that Fera engaged in anticompetitive conduct to create or to sustain its monopoly. *See Tese-Milner v. Diamond Trading Co.*, No. 04 Civ. 5203, 2014 WL 43365, at \*3 (S.D.N.Y. Jan. 6, 2014) (dismissing Section 2 claims because plaintiff failed to allege anticompetitive conduct). Anticompetitive conduct lacks a legitimate business purpose and makes sense only because it eliminates competition. *See Port Dock & Stone Corp. v. Oldcastle Northeast, Inc.*, 507 F.3d 117, 124 (2d Cir. 2007) (citation omitted). Conduct that merely harms competitors, however, while not harming the competitive process itself, is not anticompetitive. *See Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993).

Akorn alleges that consumers are paying artificially inflated prices for Bacitracin. But, as explained in *Brooke Group Ltd.*:

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Only if those higher prices are a product of nonmarket forces has competition suffered. If prices rise in response to an excess of demand over supply, or segment growth slows as patterns of consumer preference become stable, the market is functioning in a competitive manner. Consumers are not injured from the perspective of the antitrust laws by the price increases; they are in fact causing them.”

*Id.* at 232. An artificial price is one that does not reflect basic forces of supply and demand. *See U.S. C.F.T.C. v. Parnon Energy Inc.*, 875 F. Supp. 2d 233, 246 (S.D.N.Y. 2012). A “statistically unusual high (or low) price will not on that basis alone be deemed artificial.” *In re DiPlacido*, 2008 WL 4831204, at \*30 (C.F.T.C. Nov. 5, 2008) (quotation omitted). Akorn has failed to plead facts showing why Fera’s price increase resulted in an artificially high price for Bacitracin. Instead, Akorn alleges that demand for Bacitracin *increased* between 2010 and 2012 after Fera’s price increase. (Counterclaims ¶ 72.)

Akorn has also failed to plead facts sufficient to support an inference of conspiratorial conduct and does not plead actual facts that, even taken as a whole, raise a plausible inference that Fera obtained the API Supply Agreement with the “specific intent” of disrupting Akorn’s Bacitracin ANDA to maintain its *de facto* monopoly. As Akorn alleged, the [REDACTED] Agreement is the “cornerstone” of its purported antitrust injury, but this “cornerstone” provides no ability to support Akorn’s construction of non-existent antitrust injury and non-existent anticompetitive behavior. Fera did not know that Akorn had a pending Bacitracin ANDA – either prior to or at the time that Fera and [REDACTED] executed the [REDACTED] Agreement in June 2013 – because Akorn intentionally kept its submission a secret from Fera. Specifically, Akorn contractually agreed in the CMS not to source Bacitracin API for itself or anyone else except Fera. Even [REDACTED] – who shipped Bacitracin API to Akorn – did not know about Akorn’s ANDA before it was filed with the FDA. (Brick Decl. Exh. 1.)

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Akorn cannot possibly allege any specific intent by Fera to harm competition. And, without any anti-competitive or conspiratorial conduct by Fera, Akorn's claim under Section 2 of the Sherman Antitrust Act fails as a matter of law and should be dismissed.

#### IV.

#### **AKORN HAS FAILED TO STATE A CLAIM AGAINST FERA FOR TORTIOUS INTERFERENCE WITH A BUSINESS RELATIONSHIP**

Under New York law, a plaintiff asserting a claim of tortious interference with a business relationship must allege that “(1) it had a business relationship with a third party; (2) the defendant knew of that relationship and intentionally interfered with it; (3) the defendant acted solely out of malice, or used dishonest, unfair, or improper means; and (4) the defendant's interference caused injury to the relationship.” *Kirch v. Liberty Media Corp.*, 449 F.3d 388, 400 (2d Cir. 2006) (citation and quotation marks omitted). “[U]nder a tortious interference with business relationship claim, because ‘[g]reater protection is accorded an interest in an existing contract . . . than to the less substantive, more speculative interest in a prospective relationship . . . liability will be imposed only on proof of more culpable conduct on the part of the interferer’ ” than is required for an interference with contract claim. *Medtech Products Inc. v. Ranir, LLC*, 596 F. Supp. 2d 778, 815 (S.D.N.Y. 2008) (quoting *Guard-Life Corp. v. Parker Hardware Mfg. Corp.*, 50 N.Y.2d 183, 191 (1980)). Unless the “defendant engaged in conduct for the sole purpose of inflicting intentional harm on plaintiffs,” the defendant's conduct must amount to a crime or an independent tort. *Id.* (emphasis added); *see also Carvel Corp. v. Noonan*, 3 N.Y.3d 182, 190-91 (2004) (conduct that is not criminal or tortious will generally be lawful and thus insufficiently culpable to create liability for interference with nonbinding economic relations).

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Interference with another's expectation, assuming the expectation is known to the alleged interferer, is not actionable as interference with a relationship. There must at least be some showing of a similar expectancy by the counterparty (here, [REDACTED]). *See Martz v. Inc. Vil. of Val. Stream*, 22 F.3d 26, 29-30 (2d Cir. 1994) (citation omitted) (explaining in order for person to have interest in a benefit, "[h]e must have more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it"). Akorn has not alleged that it no longer has an economically advantageous relationship with [REDACTED]. The only alleged interference on Akorn's vendor-supplier relationship with [REDACTED] is that Akorn, equally among other vendors, may not receive Sterile API to commercialize Bacitracin in the U.S. Akorn's claim to a continued supply of Sterile API is nothing more than a unilateral expectation – not a relationship. The only conduct that Akorn alleges in support of its erroneous conclusion that [REDACTED] intended to supply Akorn with Sterile API for its Bacitracin ANDA is the 2008 LOA, which Akorn alleges "confirm[s] that [REDACTED] would supply Akorn with [the Sterile API] for its ANDA[.]" (Counterclaims ¶ 1.) But Akorn fails to allege any conduct on [REDACTED] part that would confirm this expectation. And, the evidence already in Akorn's possession conclusively proves just the opposite. (Brick Decl. Exh. 1.)

Specifically, in the June 2013 email exchange among [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. (See

Brick Decl. Exh. 1.) This email makes it crystal clear that Akorn did *not* have an ongoing Sterile

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API supply relationship with [REDACTED] and that Akorn did not even have a justified expectation of a supply relationship because it never advised [REDACTED] of its intent to source Sterile API from [REDACTED] in support of its Bacitracin ANDA. (*Id.*) Because Akorn has failed to allege any conduct by [REDACTED] that would confirm or support Akorn's alleged continuing supply expectation, Akorn's claimed expectation was unilateral (and thus not protected under any legally cognizable theory). As a matter of law, there was no relationship with which Fera interfered.

Nor does Akorn allege facts that support even an inference that Fera obtained an exclusive supply of the Sterile API with malicious intent or through dishonest, unfair, or improper means. *See Medtech Products Inc.*, 596 F. Supp. 2d at 815. There was nothing improper about Fera's entry into the [REDACTED] Agreement, and no allegations that the [REDACTED] Agreement was contrary to [REDACTED] economic interest. The Counterclaims similarly lack any factual allegations that [REDACTED] was forced or coerced into the [REDACTED] Agreement. The only purported "pressure" from Fera is the enforcement of the [REDACTED] Agreement's terms after the contract was formed, which fails to support Akorn's claim.

Because Akorn has failed to plead any facts that show at least an inference that Fera's sole intent in obtaining the [REDACTED] Agreement was to harm Akorn and its relationship with [REDACTED], and because the evidence in Akorn's possession conclusively refutes Akorn's alleged expectation that [REDACTED] would supply Sterile API for Akorn's Bacitracin ANDA, Akorn's counterclaim for tortious interference with business relations fails as a matter of law and should be dismissed.

**CONCLUSION**

For the foregoing reasons, Fera's motion for an order dismissing Akorn's Counterclaims should be granted in its entirety.

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Respectfully submitted,

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